Notice of Allowability	Application No.	Applicant(s)	
	10/735,419	GILBERT ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amdt of December 11, 2005*.

2. ☒ The allowed claim(s) is/are *43-45*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 0504
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Applicant's preliminary amendment of December 11, 2005, wherein Claims 1-42 have been cancelled and Claims 43-45 have been added, is acknowledged. Claims 43-45 are pending. Claims 43-45 encompass a single invention directed to an isolated or recombinant polypeptide having α-2,3-sialyltransferase activity and are hereby considered on their merits.

Priority

Both US Application 09/816,028 and US Application 09/495,406 disclose the polypeptide of SEQ ID NO: 10; however, US Application 60/118, 213 does not. Therefore, the valid priority date for the instant application is January 31, 2000, the filing date of US Application 09/495,406.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Specification

Replace the first paragraph of the specification with:

–This is a divisional application of and claims the benefit of U.S. Patent Application No. 09/816,028, filed march 21, 2001 and issued as U.S. 6,699,703 on March 2, 2004, which is a continuation-in-part of and claims the benefit of U.S. Application No. 09/495,406, filed January 31, 2000 and issued as U.S. 6,503,744 on January 7, 2003, which claims benefit of U.S.

Provisional Application No. 60/118,213, which was filed on February 1, 1999; all three applications are incorporated herein by reference for all purposes.–

Replace the legend for Figure 3, on pages 4-5, with:

–Figure 3 shows an alignment of the deduced amino acid sequences for the sialyltransferases. The OH4384 *cst-I* gene (first 300 residues, labeled Cst-1), OH4384 *cst-II* gene (identical to OH4382 *cst-II*, labeled OH4384), O:19 (serostrain) *cst-II* gene (GenBank #AF167344, labeled O:19), NCTC 11168 *cst-II* gene (labeled 11168), and an *H. influenzae* putative ORF (GenBank #U32720, labeled Hi_ORF) were aligned using the ClustalX alignment program (Thompson *et al.* (1997) *Nucleic Acids Res.* **25,** 4876-82). The shading was produced by the program GeneDoc (Nicholas, K. B., and Nicholas, H. B. (1997).–

On page 4, line 22, delete: –(URL:http//www.sanger.ac.uk/Projects/C_jejuni/)–.

On page 15, line 16, delete: –(http://www.ncbi.nlm.nih.gov/)–

On page 48, lines 2-3, delete: –the website (URL: http://www.sanger.ac.uk/Projects?c_jejuni?) of–.

On page 53, lines 16-17, delete: –(URL:http//www.sanger.ac.uk/Projects/C_jejuni/)–.

On page 56, line 1, delete: –(URL:http//www.sanger.ac.uk/Projects/C_jejuni/)–.

Title

Replace the title with: –α-2,3-sialyltransferase polypeptides–.

Claims

Claim 43: On lines 4-5, replace –at least about 80% identical to an amino acid sequence– with –at least 95% identical to the amino acid sequence–.

Claim 45: On line 4, replace – at least about 80% identical to an amino acid sequence– with – at least 95% identical to the amino acid sequence–.

Authorization for this examiner's amendment was given in a telephone interview with Beth Kelly on Septermber 23, 2005.

Allowable Subject Matter

Claims 43-45 are allowed.

The following is an examiner's statement of reasons for allowance:

All elected Claims, 43-45, are limited to an isolated or recombinant polypeptide comprising a sialyltransferase polypeptide having α-2,3-sialyltransferase activity and having at least 95% identity to the polypeptide of SEQ ID NO: 10. The recited invention is free of the art. It is noted that Eichler et al, 1999, for which Applicants are co-authors, teach the use of a *C. jejuni* 1-Neu5Ac-(2->3)-transferase (pg 4, parg 2). Applicants' declaration of September 23, 2005 states that, the sialyltransferase taught by Eichler et al is the Cst-I sialyltransferase from C. jeuni and has only 44% identity with the first 300 amino acids of SEQ ID NO: 10, which is the Cst-II sialyltransferase from C. jeuni (specification pg 60, lines 12-14; Fig 3). Therefore, Eichler et al, do not anticipate or render obvious the instant invention.

The utility of the polypeptide of SEQ ID NO: 10, as having α-2,3-sialyltransferase activity, is credible based on expression in heterologous host cells and analysis by an enzymatic assay (Table 5). It is well known in the art that saccharide moieties regulate the interaction between liposaccharides and proteins in a wide variety of processes such as fertilization, molecular targeting, intracellular recognition, and viral, bacterial, and fungal pathogenesis (Roth et al, 1995; pg 2). Liposaccharides are, thus, commercially important for regulating said

processes. *C. jejuni* is one of the most prevalent causes of bacterial diarrhea and sialylation affects immunogenicity and serum resistance (Guerry, 2000). Hood et al, 2001 teach that a α-2,3-sialyltransferase is critical for killing of H. influenzae by human serum (Fig 5). Thus, a person of ordinary skill in the art would believe that more likely than not, the α-2,3-sialyltransferase of the instant invention has utility in the identification of inhibitors useful for treatment of *C. jejuni* infection as well as for the production of liposaccharides that can also be used for developing a treatment for *C. jejuni* infection.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.

Art Unit 1656

SHERIDAN SWOPE, Ph.D.
PATENT EXAMINER